UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF AHMET BEDESTANI, M.D.

INTRODUCTION

Plaintiffs do not challenge Dr. Bedestani's expertise as a pelvic surgeon. *See generally* Plaintiffs' Motion to Exclude [Doc. No. 6884]) and Memorandum in Support [Doc. No. 6888] ("Pls.' Mot."). In fact, they do not discuss his qualifications at all or mention that he is a board-certified in Obstetrics and Gynecology, Female Pelvic Medicine and Reconstructive Surgery and Gynecology. Ex. A, Bedestani Report at 2. He has more than 15 years' experience in the diagnosis and treatment of female urinary incontinence and pelvic disorders and actively performs prolapse and incontinence surgeries. *Id.* In fact, he has implanted thousands of patients with Gynemesh or Prolene mesh. *Id.* at 24.

Despite Dr. Bedestani's extensive experience and his review of considerable peer-reviewed medical literature, including Cochrane reviews, randomized control trials, the Prosima device IFU, patient brochure, and professional education materials, *see, e.g.*, Bedestani Report at

14-27; Ex. B, Bedestani Reliance List,[1] Plaintiffs first disdainfully attack Dr. Bedestani's medical education, which he obtained outside of the United States, arguing that despite attending a medical school fully accredited in its own country and passing multiple United States board certifications, Dr. Bedestani is unqualified to testify as an expert in this case. Second, Plaintiffs seek to preclude his opinions, based upon his years of experience, that the warnings included in the Prosima device were adequate. Third, Plaintiffs attempt to preclude Dr. Bedestani from offering testimony that the Prosima's design is not defective. Finally, Plaintiffs attempt to exclude Dr. Bedestani's opinion that Prosima was the state of the art when it was on the market. None of Plaintiffs' arguments has merit and their Motion should be denied.

ARGUMENT

I. Standard for admissibility of expert opinion testimony.

Ethicon incorporates by reference the standard of review for Daubert motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D. W. Va. July 8, 2014).

II. Dr. Bedestani is well qualified to offer opinions on the safety and efficacy of Prosima and his opinions are grounded in his training and experience as well as his review of the medical literature.

Dr. Bedestani is the Director of East Jefferson Urogynecology in Metairie, Louisiana. *See* Bedestani CV, Exhibit C. He has also served as an Assistant Professor in Female Pelvic Medicine and Reconstructive Surgery at the Louisiana State Health Sciences Center's Department of Obstetrics and Gynecology. *See id.* He is board certified by the American Board of Obstetrics and Gynecology with a subspecialty certification in Female Pelvic Medicine and Reconstructive Surgery and is a Diplomate of the American Board of Obstetrics and

[1] Although Plaintiffs attached Dr. Bedestani's Report to their Motion, they did not include his reliance lists or exhibits to that Report.

Gynecology. *See id.* He has published and presented widely on the subject of female pelvic medicine. *See id.* He has performed many types of surgery for the correction of stress urinary incontinence and pelvic organ prolapse, including native tissue repair, mesh-augmented autologous fascial slings, augmented repair of pelvic organ prolapse, open and laparoscopic Burch uretheropexies, and synthetic mesh slings. Ex. A, Bedestani Report at 2. He has performed over 1000 midurethral sling surgeries and over 1000 surgeries to correct pelvic organ prolapse. *See id.* He cited numerous studies in his report supporting his opinions that Prosima is safe and effective. *See id.* at 15-28.

a. Plaintiffs offer no reason to exclude Dr. Bedestani's testimony on safety and efficacy based upon his medical schooling

Plaintiffs first seek to exclude Dr. Bedestani's opinions on the safety and efficacy of Prosima because he received his medical education outside of the United States. They offer no explanation of why receiving one's medical degree from an institution outside of the United States disqualifies one from becoming an expert in one's field. In fact, Dr. Bedestani, after receiving a Bachelor of Science, Certificate of Anatomy, and Master of Science from St. Louis University in Missouri, *see* Ex. A, received his medical degree from Ross University School of Medicine on the island of Domenica. *See* Ex. C, 9.21.18 Dep. of Ahmet Bedestani, M.D. Tr. ("Bedestani Dep.") at 80:7-12. Ross University was fully accredited by the Government of Domenica. *Id.* at 81:6-8. Plaintiffs attempt to cast aspersions on Dr. Bedestani's medical training by implying that he is not qualified to testify as an expert simply because he was not accepted to medical school within the United States,[2] but they offer no evidence that Dr. Bedestani's education renders him unfit to practice medicine and opine on medical topics. Dr.

[2] Plaintffs argue that Dr. Bedestani was rejected "twice" from every medical school in the United States but conspicuously omit Dr. Bedestani's comment that he was speaking "in jest." Ex. C, Bedestani Dep. Tr. at 79:22-24.

Bedestani is fully licensed to practice medicine in the United States. *See* Ex. A. Plaintiffs' arguments on this topic should be rejected in full.

b. Plaintiffs offer no reason to exclude Dr. Bedestani's testimony based on his use of Prosima or his prior history as an expert

Plaintiffs make the puzzling argument that Dr. Bedestani cannot testify as to the safety and efficacy of Prosima because he "never used the Prosima device as a physician." Pls.' Mot. at 5. Dr. Bedestani testified that he has had experience using all available mesh kits. Ex. C, Bedestani Dep. Tr. at 73:25-74:5. He used the Prosima device in particular from 2009-2011, at which time he was in his fellowship. *Id.* at 25:25-26:19 (testifying that he implanted the Prosima "as soon as [he] could obtain the device"); 97:12-98:7; Ex. D, Bedestani CV. He stopped using the device in 2011 because he was not practicing at that time and had gone into academia. *Id.* at 108:18-109:10. Also around that time, Ethicon ceased marketing the Prosima. *Id.* at 97:12-98:7; 108:18-109:10. In other words, Plaintiffs fault Dr. Bedestani for not using a device while he was not practicing and while the device was not marketed. Pls.' Mot. at 5. The Court should reject these arguments.

So, too, should the Court reject Plaintiffs' argument that simply because Dr. Bedestani has not testified previously as an expert, he is not qualified to do so. Pls.' Mot. at 5. Plaintiffs cite no law stating that an expert may be qualified as such only if he or she has previously testified as an expert. This is plainly not the case under the relevant Rules of Evidence. *See* Fed. R. Evid. 702 ("A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the

testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.").

Plaintiffs next argue that Dr. Bedestani is not qualified to testify about safety and efficacy of Prosima because he does not use transvaginal mesh currently in his practice. Pls.' Mot. at 6. But Plaintiffs ignore the facts that he has performed over 1000 midurethral sling surgeries and over 1000 surgeries to correct pelvic organ prolapse. Ex. A, Bedestani Report at 2. Plaintiffs chose not to explore with Dr. Bedestani at his deposition the reasons he currently does not use mesh. In fact, although Dr. Bedestani does currently do "a lot of" abdominal sacrocolpopexy in his practice, he does not consider it the "gold standard for treatment of pelvic organ prolapse." Ex. C, Bedestani Dep. Tr. at 60:10-61:18. Simply because Dr. Bedestani is not *currently* using transvaginal mesh, for reasons not elucidated by Plaintiffs, is not a reason to disqualify him in light of his extensive training and experience with mesh products. Plaintiffs also appear to argue that because Dr. Bedestani is not currently using Prosima, he has "not employed . . . the same level of intellectual rigor" to his practice that he does to his opinions. Pls.' Mot. at 6. But Prosima is not currently on the market—Dr. Bedestani cannot currently use it. Plaintiffs' argument should be rejected.

c. Dr. Bedestani has adequately studied the literature on degradation.

Plaintiffs next attempt to argue that Dr. Bedestani is not qualified to testify as to the safety and efficacy of Prosima because he "has not studied key evidence on the central issue of degradation." Pls.' Mot. at 6. Plaintiffs arrive at this conclusion by arguing that Dr. Bedestani billed only 64.4 hours for his work on this case. *Id.* at 7. They completely ignore the countless hours that Dr. Bedestani testified that he put into researching these issues and understanding this device, for which he felt it would be improper to bill to Ethicon. Ex. C, Bedestani Dep. Tr. at 6:21-7:4; 13:5-10 (testifying that hours billed were only "a fraction of the time" that he spent on

these opinions). Further, Dr. Bedestani cites several studies and authorities on the subject of degradation in his report, *see, e.g.*, Ex. A, Bedestani Report at 25-26; Ex. C, Bedestani Dep. Tr. at 12:1-13:1. Plaintiffs fault Dr. Bedestani for not being familiar with certain cherry-picked studies regarding degradation, *see* Pls.' Mot. at 7-8. The existence of claimed contrary studies is fodder for cross examination, not a basis to exclude Dr. Bedestani's opinions as unreliable when they are based both on his considerable personal experience as well as medical literature and studies. *See Carroll v. Boston Scientific Corp.*, Civ. A. No. 2:13-cv-11601, 2016 U.S. Dist. LEXIS 60335, at *10-11 (S.D.W. Va. May 6, 2016) (expert's failure to consider document goes to weight, not admissibility, of opinion testimony); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("the court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct.").

Further, the Court rejected a similar argument in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521 (S.D. W. Va. May 19, 2016). The plaintiff in that case challenged defense expert Stephen Badylak, M.D.'s competence to testify about the safety and efficacy of polypropylene mesh devices on the basis that Dr. Badylak had admitted that he had not performed a "comprehensive review" of the scientific literature related to the defendant's devices." *Id.* at *40. The Court, however, noted that Dr. Badylak's report demonstrated that he "reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices," and that "[i]f there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Id.*; *see also id.* at *8 (S.D. W. Va. Apr. 28, 2016) (finding that "to the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis's opinions, not their

admissibility" and that "[t]he defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions").

In short, a surgeon with Dr. Bedestani's experience is allowed to examine the literature and offer such an opinion. *See Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *24 (S.D. W. Va. May 5, 2015) (rejecting attempt to exclude testimony by an obstetrician-gynecologist on the "safety and effectiveness" of midurethral slings and holding that the clinician's extensive experience implanting the devices "along with his review of the existing literature, provides a reliable basis for his opinions on the safety and efficacy of the Advantage Fit."). "If there are certain device-specific publications that [Plaintiffs claim that Dr. Bedestani] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Trevino*, 2016 WL 2939521, at *40

III. Dr. Bedestani is qualified to testify as to Prosima's warnings.

Plaintiffs seek to exclude Dr. Bedestani's opinions that the Prosima's Instructions for Use (IFUs) were "adequate, helpful, and not misleading in terms of its indications, instructions, and warnings and adverse reactions." Ex. A, Bedestani Report at 27. Dr. Bedestani further opines that surgeons "rely on the education, training, experience and review of the medical literature" to understand surgical technique and the potential risks of surgery before performing it. *Id.* They are also "expected to know without reliance on a manufacturer's IFU what are the risks and benefits of performing surgery." *Id.* Information about the frequency and severity of potential complications is, according to Dr. Bedestani, "integral to a surgeon's education, training, experience, and review of medical literature." *Id.*

Plaintiffs complain that Dr. Bedestani has not drafted or reviewed a medical device's product label. Pls.' Mot. at 8-9. But "doctors are fully qualified to opine on the medical facts

and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D. W. Va. Apr. 24, 2015). This is not prohibited "state of mind" testimony, but is, rather, proper "common knowledge" testimony.

Dr. Bedestani's testimony on Defendants' IFUs and warnings is consistent with the governing legal standard and should therefore be admitted in its entirety. The legal principle that controls here is that a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting "sophisticated user" defense in §388). The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of person whose use is at issue in the particular case. *Johnson v. American Standard, Inc*., 179 P.3d 905, 914 (Cal. 2008) (sophisticated user "knew or should have known" of the danger).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). In fact, the FDA device regulations say that information may be omitted from labeling:

> if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.

21 C.F.R. §801.10(c) (emphasis added). *See also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc*., 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd*., 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).

The IFUs at issue here restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. The Prosima IFU says that "Federal (USA) law restricts this device to sale by or on the order of a physician. Training on the use of the GYNECARE PROSIMA Pelvic Floor Repair System is recommended and available." Ex. E, Prosima IFU at 10. It further states that "[u]sers should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROSIMA Systems." *Id.* at 12. So the important question with respect to the plaintiffs' failure to warn claim is what "hazards" were "commonly known" to surgeons familiar with traditional non-mesh SUI surgery and mesh surgery before Prosima was introduced.

Dr. Bedestani is qualified by his experience and her examination of the literature to identify the risks that are commonly known and give the opinion that the IFU adequately discloses those that might not be. His deposition testimony makes clear that he, as a pelvic floor surgeon, is qualified to assess potential risks and complications associated with pelvic floor surgery and "hold[s] [him]self in a position to judge the application of technology when it comes to the realm of pelvic surgery." Ex. C, Bedestani Dep. Tr. at 113:2-18. This includes

"understanding and being knowledgeable about the potential adverse events that could happen following a prolapse repair surgery." *Id.* at 113:20-114:25.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court, in particular, has made clear that a physician can draw upon his clinical experience and review of relevant literature to give opinions on a product's safety and efficacy. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products). It has found the same with respect to an expert offering a risk/benefit opinion. *See Winebarger*, 2015 WL 1887222, at *7.

"[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger*, 2015 WL 1887222, at *15. A physician is qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues). Moreover, a physician is qualified to testify about the adequacy of IFUs from a clinical perspective, despite lack of familiarity with FDA regulations and requirements for warnings, or prior experience drafting IFUs. *Id.* at *6-7, 15 (finding Dr. Galloway qualified to provide opinion on IFUs based on clinical experience despite lack of familiarity with FDA rules or regulations for warnings).

Like Drs. Shull and Galloway in *Winebarger*, Dr. Bedestani does not offer opinions about how the warnings were developed or on the regulatory requirements or processes. Instead, he seeks to testify about the completeness and accuracy of the warnings from his clinical perspective. Dr. Bedestani is well qualified by his training, education, review of the literature, and clinical experience to testify as to the risks and benefits of Prosima that were known to pelvic floor surgeons regardless of their inclusion in the product's IFUs.

IV. Dr. Bedestani is qualified to testify as to Prosima's design.

Dr. Bedestani opines that, to the extent that Plaintiffs' experts opine that native tissue repairs are "safer alternative designs" to Prosima and Gynemesh PS, he disagrees because "[o]ther surgeries are not alternative designs" for these products. Ex. A, Bedestani Report at 27. He also states that he is aware of no other alternative design for mesh that "would have prevented or significantly reduced the potential complications of mesh erosion, pain, dyspareunia, scarring, contraction, infection, and urinary problems." *Id.* He therefore concludes that these "design defect allegations of plaintiff experts are without merit." *Id.* at 28. Plaintiffs challenge none of these specific conclusions or reasoning, arguing instead that Dr. Bedestani is unqualified to offer any opinions as to Prosima's design at all because, they argue, these opinions are based on his opinions that polypropylene does not degrade and because he does not currently use mesh in his practice. Pls.' Mot. at 10. As set forth above, these arguments are meritless and certainly do not preclude Dr. Bedestani from offering opinions regarding what is or is not a mesh "design" and whether he personally is aware of a mesh design that would have prevented the conditions listed above.

Indeed, Plaintiffs recognize the futility of their argument because they conceded that their own experts have been permitted to opine as to mesh properties as they relate to design-defect

claims. Pls.' Mot. at 10. They try to distinguish those decisions by arguing that their experts, such as Dr. Rosenzweig, have "vastly superior experience," as demonstrated by "perform[ing] more than 1,000 pelvic floor surgeries." *Id.* Under Plaintiffs' formulation of what would qualify a surgeon to testify as to mesh properties, Dr. Bedestani, having performed over 1,000 midurethral sling surgeries and over 1,000 surgeries to correct pelvic organ prolapse, *see* Ex. A, Bedestani Report at 2, is well qualified to do the same. The Court should reject this argument.

V. Dr. Bedestani's testimony that Prosima was the "state of the art" when it was on the market is reliable.

Finally, Plaintiffs seek to exclude Dr. Bedestani's opinion that Prosima was the "state of the art" when it was on the market. Pls.' Mot. at 11-12. Their primary argument in support of this position is that Dr. Bedestani "does not offer any comparison of the Prosima with other devices." *Id.* This is incorrect. Dr. Bedestani testified as to the distinguishing features of Prosima in his deposition:

> Q. [T]he Prosima uses the VSD, or vaginal support device mechanism; correct?
>
> A. That is correct.
>
> Q. And the design of the Prosima, which includes the VSD device, is unique to any other transvaginal mesh POP kit ever marketed in the United States. Fair?
>
> A. Absolutely no. The vaginal support device was only involved with Prosima. There was no other splinting-type device that I was aware of for any other marketed transvaginal mesh kit: Apogee, Perigee, Elevate, Pinnacle, Uphold.
>
> . . .
>
> Q. But as far as the splinting—the splint device, that was unique to the Prosima correct?
>
> A. Yes.

> Q. But there's—there's no other transvaginal mesh product that you're aware of that uses the type of design that Prosima does, correct?
>
> A. That is correct, sir.

Ex. C, Bedestani Dep. Tr. at 20:10-21:9. Further, Dr. Bedestani testified that he has used all available pelvic organ prolapse mesh kits, and "violation of the sacrospinous ligament neurovascular complex is something that all of these mesh kits have in common. Prosima, and Prosima only, is the only one that did not violate that structure." *Id.* at 74:22-75:4; *see also* Ex. A, Bedestani Report at 3 ("All [graft kits] except Prosima mimicked certain aspects of specific native tissue repairs in violating the sacrospinous ligament complex."). Dr. Bedestani has offered deposition testimony as to other devices available to support his opinion that Prosima was the "state of the art" when it was on the market.

Plaintiffs' other arguments here again are founded upon their contention that Dr. Bedestani allegedly failed to review their preferred materials on degradation. For the reasons set forth above, this is not a basis to exclude Dr. Bedestani's opinions but rather is fodder for cross-examination. *See Carroll v. Boston Scientific Corp.*, Civ. A. No. 2:13-cv-11601, 2016 U.S. Dist. LEXIS 60335, at *10-11 (S.D.W. Va. May 6, 2016) (expert's failure to consider document goes to weight, not admissibility, of opinion testimony); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("the court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct.").

CONCLUSION

For the reasons set forth above, the Court should deny Plaintiffs' Motion to Exclude the General Causation Opinions of Defense Expert Ahmet Bedestani, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this date, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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